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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,657	02/08/2002	Srinivasan Ramanathan	2560-1-001 N	3296
23565	7590	12/11/2003	EXAMINER	
KLAUBER & JACKSON 411 HACKENSACK AVENUE HACKENSACK, NJ 07601			AUDET, MAURY A	
			ART UNIT	PAPER NUMBER
			1654	
DATE MAILED: 12/11/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/072,657

Applicant(s)

RAMANATHAN ET AL.

Examiner

Maury Audet

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 69-193 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 69-193 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept.

In accordance with 37 CFR 1.142, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 68-107, drawn to a method for delivery of agents from an initial bodily compartment to at least one target bodily compartment, classified in class 424, subclass 1.69.
- II. Claims 108-137, drawn to compositions, trancompartmental delivery promoting, comprising a polymer and covalently bound to a therapeutic or diagnostic agent, classified in class 514, subclass 2.
- III. Claims 138-164, drawn to compounds of the general formula $(X)_o-(Y)_m-(\text{linker})_n$ **[Formula A]**, classified in class 530, subclass 300+.
- IV. Claim 165, drawn to a method for making (identifying/screening) a suitable compound, of the general formula $(X)_o-(Y)_m-(\text{linker})_n$ **[Formula A]**, for therapeutic or diagnostic use, classified in class 435, subclass 7.1.
- V. Claims 166-176 and 178-192, drawn to compounds of the general formula $(Y)_m-(\text{linker})_n-(X)_o$ **[Formula B]**, classified in class 530, subclass 300+.

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- VI. Claims 177, drawn to a method for oral delivery of agents, of the general formula $(Y)_m-(\text{linker})_n-(X)_o$ [Formula B], namely a protein or peptide, to an animal, classified in class 424, subclass 9.34.
- VII. Claim 193, drawn to a method for making (identifying/screening) a suitable compound, of the general formula $(Y)_m-(\text{linker})_n-(X)_o$ [Formula B], for therapeutic or diagnostic use, classified in class 435, subclass 7.1.

[Note: The preamble of claims 70, and 174-175 need to be amended to be consistent with the respective group they depend from. Should a group be elected to which one or more of these claims is within, amendment thereof of the preamble is required, as part of the response to this election.]

The inventions are distinct, each from the other because of the following reasons:

Inventions I and VI and III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the methods of use may be practiced by any of myriad of compounds (agent of Formula A or B).

Inventions IV and VII and III and V are related as process of making (identifying/screening) and product made (compound (agent of Formula A or B)). The inventions are distinct if either or both of the following can be shown: (1) that the process as

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claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the process as claimed can be used to make other and materially different product, namely any one of the myriad of compounds of Formula A or B.

Inventions II, III, and V are related as compositions (polymer covalently bound to agent) and compounds, both containing an agent. However, the compounds do not contain a polymer, and are thus distinct from the compositions. Furthermore, the compounds of Formula A (Group III) and Formula B (Group V) each contain distinct compound agents therein, and are thus distinct not only between the Groups, but also internally with in each group. (See also below, regarding election of specific compound or compositions as drawn to the elected invention (group)).

Inventions I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a method of use directed to delivery of an agent from any body compartment (not just orally) (I) or a method of use directed only to oral delivery of an agent (V).

Inventions IV and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a method of making (identifying/screening) an agent of Formula A (IV) or a method of making (identifying/screening) an agent of Formula B (VII).

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Inventions I and VI and IV and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are alternative methods having different modes of operation, different functions, and different effects; namely methods of use (I and VI) and methods of making (identifying/screening) (IV and VII).

The composition of Invention II is not used in any of the methods of Invention I and VI or IV and VII. Therefore, Invention II is distinct from Inventions I and VI and IV and VII.

ELECTION OF A COMPOUND/COMPOSITION OF THE INVENTION

The myriad of compositions and compounds are distinct invention(s) themselves, which require a separate search, which is not coextensive with a search of any of the other compositions/compounds. Therefore, an individual structure and/or sequence search is required of each individual compound. Additionally, as part of the electing one of Groups I-VII as the elected invention, Applicant is required to **elect a specific composition (one compound structure of a polymer covalently bound to agent) or compound (agent, one compound structure of Formula A or B)** as drawn to the elected group, to which the elected invention will be examined on the merits as drawn to. **This requirement is not to be taken as an election of species, but rather as an election of a single invention, since each compound/composition is assumed to be a patentably distinct invention, in the absence of evidence to the contrary.**

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The several inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference, which would anticipate the invention of one group, would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application. Restriction for examination purposes is therefore proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 703-305-5039. The examiner can normally be reached from 7:00 AM – 5:30 PM, off Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached at 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-1234 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

MA

November 26, 2003


BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600